

IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

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Case No. 2:11-cv-1016

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In Re: Ohio Execution Protocol Litigation,

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30(B)(6)

Deposition of: KARRIE SOUTHARD

Date and Time: Tuesday, June 11, 2019
9:53 a.m.

Place: Federal Public Defender's
Office
10 West Broad Street
Suite 1020
Columbus, Ohio

Reporter: Julieanna Hennebert, RPR, RMR
Notary Public - State of Ohio

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1 KARRIE SOUTHARD,
2 being by me first duly sworn, as hereinafter
3 certified, deposes and says as follows:

4 EXAMINATION

5 Q. Hi. Can you start with your name, please.

6 A. Karrie Southard.

7 Q. Do you want to spell your last name?

8 A. S-o-u-t-h-a-r-d.

9 Q. Ms. Southard, my name is Adam Rusnak, I'm
10 an attorney for Mr. Cleveland Jackson. With me are
11 my co-counsel Allen Bohnert, Paul Bottei.

12 Do you understand you're here to be
13 deposed today?

14 A. Yes.

15 Q. And that you're appearing as a 30(B)(6)
16 witness?

17 A. Yes.

18 Q. Do you know what that means?

19 A. Means that I am speaking on behalf of the
20 Agency the Board of Pharmacy.

21 Q. Have you ever been deposed before?

22 A. Not deposed but I've testified in a public
23 hearing before the Board of Pharmacy.

24 Q. So I think it's normal in depositions to
25 have a couple, sort of remind people of the rules.

1 If you don't understand any question I ask, please
2 just say so. We have to try not to talk over each
3 other. And we have to try to use words, not nod our
4 head, for the court reporter.

5 A. Understood.

6 Q. I want to start with what we'll say is
7 Exhibit 1, that's the subpoena in this case.

8 MR. RUSNAK: Do you have that, Allen?

9 Q. I would direct your attention to I guess
10 Attachment 1.

11 (EXHIBIT 1 MARKED.)

12 Q. I suppose the start of the subpoena
13 notices what is marked as page 4. Have you seen this
14 before?

15 A. I have.

16 Q. And on I guess two pages later Attachment
17 1, have you read this before?

18 A. I have.

19 Q. And in particular part 1 there, are you
20 familiar with that deposition topic?

21 A. Yes.

22 Q. And is that what you're prepared to talk
23 about today?

24 A. Yes.

25 Q. One question I meant to ask, I'm sorry I

1 skipped it. The Board, the acronym for the Board is
2 the Ohio State Board of Pharmacy?

3 A. State of Ohio Board of Pharmacy.

4 Q. See, I already got it wrong. State of
5 Ohio Board of Pharmacy.

6 A. Yes.

7 Q. So do you normally say SOBP or just Board?
8 Maybe we can go with "the Board"?

9 A. "Board" would be.

10 Q. I think "Board" would be easier to say.

11 A. Yes.

12 Q. I can see how that's an acronym that's
13 unfortunate.

14 So in preparing for the deposition today
15 on this topic, topic No. 1, did you review any
16 documents to get ready?

17 A. I did. Mostly the Ohio Revised Code, Ohio
18 Administrative Code, and documents publicly available
19 on our website.

20 Q. Did you talk to anyone?

21 A. I did, I spoke with our legal counsel
22 that's represented here.

23 Q. How long do you think you spent preparing?

24 A. Probably under four hours but over two.

25 Q. And when did you do that preparation; this

1 week, last week maybe?

2 A. It was the week before we were originally
3 scheduled.

4 Q. Do you feel like that information is still
5 fresh in your mind now?

6 A. Absolutely, yes.

7 Q. And you said you have never done a
8 deposition before, so is it fair to say you've never
9 done a 30(B)(6) deposition before?

10 A. That is correct.

11 Q. But I think you indicated already that you
12 understand that you're speaking on behalf of the
13 Board.

14 A. I do.

15 MR. APPEL: May I represent that she is
16 the 30(B)(6) witness for Question No. 1 that you've
17 identified on Attachment 1 of the subpoena.

18 MR. RUSNAK: Thank you.

19 Q. And if there should come a time in our
20 questions where you find you're speaking on behalf of
21 yourself, please just say so.

22 A. Understood.

23 Q. In fact I do want to ask you a couple
24 questions about yourself before we go any farther,
25 which is just what is your current role with the

1 Board?

2 A. My official title is Deputy Director 5,
3 unofficially at the Board of Pharmacy I'm Director of
4 Licensing.

5 Q. How long have you been at that role?

6 A. At that role just about a year.

7 Q. And before that were you also with the
8 Board?

9 A. I was as licensing administrator, which
10 reports directly to the Director of Licensing.

11 Q. So what does your current role sort of
12 involve?

13 A. I oversee the day-to-day functions of the
14 Licensing Department, which has a licensing
15 administrator and six licensing coordinators who
16 process the applications, involved in rule review,
17 answering questions from licensees and potential
18 applicants, and overall representing the Licensing
19 Department with the staff and overall duties of the
20 Board.

21 Q. So I think we're here today mostly to
22 focus on a particular kind of license. Could you
23 sort of tell me in brief what a TDDD, can I call it
24 that?

25 A. You can, or we can refer to it just as a

1 terminal distributor, whichever you prefer.

2 Q. I just wanted to avoid saying "terminal
3 distributor dangerous drugs." Terminal distributor
4 license.

5 A. So a terminal distributor license is
6 required for any entity in Ohio that possesses
7 dangerous drugs or any entity outside of Ohio that is
8 shipping dangerous drugs into Ohio patient specific.

9 Q. An entity outside of Ohio, would that be
10 like a mail order pharmacy?

11 A. Potentially, yeah.

12 Q. Can you tell me a couple other examples?

13 A. Typically they are mailing it in. Some do
14 have courier service into Ohio. So technically they
15 wouldn't be mailing.

16 Q. I understand. But a terminal distributor
17 license is not just a pharmacy; is that right?

18 A. That is correct.

19 Q. What other kind of entities are there?

20 A. An emergency medical service,
21 veterinarian, a doctor's office where you go to get
22 your flu vaccine, those are other types of terminal
23 distributors.

24 Q. How is that different from a wholesale
25 distributor of drugs?

1 A. So wholesale distributor is distributing
2 dangerous drugs at wholesale. So they're not going
3 to the end user, the patient, they would be going to
4 other wholesale distributors or terminal
5 distributors. A terminal distributor, dangerous
6 drugs are typically going to the end user, which is
7 what we refer to as a patient.

8 Q. And I am aware that for at least the
9 terminal distributor license there are two
10 categories; Category 2 and Category 3.

11 A. Correct.

12 Q. Is there a similar distinction for the
13 wholesale distributor?

14 A. It is the same distinction.

15 Q. And can you explain that distinction?

16 A. So Category 2 terminal distributor or
17 wholesale distributor allows any entity to possess,
18 distribute, sell dangerous drugs which are not
19 controlled substances. And Category 3 allows the
20 distribution of all dangerous drugs including
21 controlled substances.

22 Q. So is that all controlled substances?

23 A. Correct.

24 Q. All except Schedule 1.

25 A. Sure.

1 Q. And Schedule 1 is because those drugs are
2 illegal.

3 A. Correct.

4 Q. I think I knew that but I'm glad I got
5 that right.

6 A. I will clarify, except now that we have
7 the Medical Marijuana Control Program in the state of
8 Ohio, that, but speaking directly to terminal and
9 wholesale distributors, it would be all except
10 Schedule 1.

11 Q. So we talked a little bit about you
12 mentioned already instate and out of state.

13 A. Correct.

14 Q. Let's focus on terminal distributors. In
15 what ways are their sort of applications different in
16 general?

17 A. So one of the ways that the application is
18 different for an out-of-state terminal distributor,
19 the entity must first possess licensure in their
20 resident state or home state where the business
21 entity is actually located.

22 Q. Licensure with their own state Board of
23 Pharmacy?

24 A. Whichever state licensing authority.

25 Q. As appropriate.

1 A. Yes.

2 Q. I see. So I think we'll get into the
3 details here in a second. How does an entity apply
4 for a terminal distributor license?

5 A. So our license applications are all online
6 through E-license Ohio, which most of the boards and
7 commissions in Ohio use that system. So they create
8 a profile and start the application which is all
9 submitted online.

10 Q. Let me first draw your attention to,
11 Allen, if you could give me this one which I've
12 marked as No. 2.

13 (EXHIBIT 2 MARKED.)

14 Q. So this is a document that the Board
15 produced to us, to Mr. Jackson in relation to this
16 subpoena. Do you recognize this?

17 A. I do.

18 Q. Can you tell me what it is?

19 A. It is our former paper application before
20 we went into the E-license Ohio system. So this
21 would be the application for pharmacies, both instate
22 and out-of-state pharmacies.

23 Q. And you say "former" meaning what?

24 A. We no longer accept paper applications
25 since we are now on E-license Ohio.

1 Q. So for how long was this one relevant or
2 until when?

3 A. We went live on E-license Ohio on
4 April 21, I would have to look, it was late April of
5 2018. I would have to look back at the specific
6 date.

7 Q. 2018 though was the point.

8 A. April of 2018, yes.

9 Q. And so any entity applying for a terminal
10 distributor license now would not use this document
11 that I produced to you.

12 A. That is correct.

13 Q. I think they would use this document.
14 (EXHIBIT 3 MARKED.)

15 Q. It's called Initial Application at the
16 top.

17 (EXHIBIT 4 MARKED.)

18 A. Can you repeat your question, please?

19 Q. Yeah, I will definitely ask the question
20 again.

21 A. Thank you.

22 Q. This document, these two documents
23 Exhibits 3 and 4 were also provided to us by the
24 Board.

25 A. That is correct.

1 Q. Can you tell me what these are?

2 A. These are sample applications of the
3 questions and instructions that are included in
4 E-license Ohio.

5 Q. So is it fair to say this is a reasonable
6 sort of facsimile of what it would look like, the
7 same questions I would answer if I went on the
8 website?

9 A. Correct.

10 Q. So if we talk about these questions, am I
11 correct in saying we're talking about the questions
12 that would be asked in the E-license process?

13 A. Yes.

14 Q. And I think Exhibit 3 is for an instate
15 pharmacy?

16 A. That is correct.

17 Q. And Exhibit 4 is for an out-of-state
18 pharmacy.

19 A. That is correct.

20 Q. So not to be repetitive, but if I were an
21 out-of-state pharmacy seeking an Ohio terminal
22 distributor license I would go on the E-license
23 online website and I would be asked questions that
24 are sort of encapsulated in Exhibit 4.

25 A. If you selected the correct license type,

1 yes.

2 Q. If I didn't make a mistake?

3 A. Correct.

4 Q. And I wanted to give you one important
5 exhibit before we sort of look at this one and that's
6 this one. I don't think that we got this from you
7 but I think, well, you can tell me what it is.

8 (EXHIBIT 5 MARKED.)

9 Q. So do you recognize what is Exhibit 5?

10 A. I do.

11 Q. And can you tell me who that is?

12 A. It is an E-license Guide that is publicly
13 available on our website. And we have a few of these
14 for the different license types, so this appears to
15 be pulled from our terminal distributor licensing
16 page.

17 Q. And I see it says updated April 23, 2018.

18 A. Correct.

19 Q. Is that the most recent version?

20 A. As far as I know.

21 Q. So an out-of-state maybe in this case,
22 would this Exhibit 5 -- strike all that.

23 Would Exhibit 5 be for an instate or
24 out-of-state pharmacy seeking license?

25 A. Yes.

1 Q. So if I were a pharmacy applying for a
2 license and I went to the E-license website this
3 would be the first thing I saw, Exhibit 5?

4 A. No, you would not see this E-license Guide
5 on any license. This is on the Board of Pharmacy's
6 website. E-license is a separate web service
7 supported by the Department of Administrative
8 Services.

9 Q. Why might I look at Exhibit 5 then?

10 A. If you needed assistance in completing the
11 application, identifying what type of application you
12 needed in this step-by-step process to apply.

13 Q. Is it fair to say this is sort of guidance
14 for completing?

15 A. Correct.

16 Q. I understand. Is it right to say that
17 this document, Exhibit 5, sort of helps a pharmacy or
18 an applicant for a terminal distributor license
19 navigate the application process?

20 A. Yes.

21 Q. Let's look at Exhibit 4 then.

22 A. Okay.

23 Q. I just want to walk through a couple of
24 the steps here to make sure that we understand what
25 the application entails.

1 A. Okay.

2 Q. So on the top of the first page, I should
3 have highlighted your copy but I didn't, on the top
4 of the first page it says "Eligibility: Is your
5 business a pharmacy located outside of Ohio that
6 ships, mails, or delivers, answer yes or no.

7 A. Uh-huh.

8 Q. So what does that question help us
9 determine? Is that question if this is the right
10 thing for us?

11 A. If it's the correct license type.

12 Q. I see. And so the answer is yes, this is
13 the correct license type.

14 A. Correct.

15 Q. And then down at the bottom of the page it
16 has Category 2 and 3, and these are the categories we
17 talked about previously?

18 A. Yes.

19 Q. I think the next couple pages are sort of,
20 well, maybe you can sort of describe the next couple
21 pages for us instead of me talking the whole time.

22 A. So as you see at the end of the first page
23 where you just referenced "category," that is part of
24 the application instructions which are found on the
25 E-license screen below the eligibility question.

1 And the instructions include up to, the
2 pages aren't numbered but it's the second page
3 through the middle of the page, the complete the
4 instruction and then it begins the application, which
5 starts with basic business information.

6 Q. And that includes the business name, what
7 they're registered as, on the next page what their
8 website is.

9 A. Correct.

10 Q. I think maybe the next section starts
11 where it says Background.

12 A. That is correct.

13 Q. And what is that section about?

14 A. So these are the, a section where a
15 pharmacy or a business applicant, this applies to
16 more than just pharmacies, can add their applicant,
17 owners, and responsible person for their business in
18 their application.

19 Q. So maybe you can help me understand the
20 difference between the applicant and the responsible
21 person.

22 A. So the applicant is any individual who is
23 eligible to sign on behalf of the business. It does
24 not necessarily always pertain to the person filling
25 out the application, they can be different people.

1 A responsible person is someone who is by
2 Ohio rule required to serve as, sorry for lack of
3 terminology, but who's responsible for the license,
4 which is required by Ohio Administrative Rule and the
5 Board determines who is eligible to serve as the
6 responsible person by license type.

7 Q. So I don't want to oversimplify it but is
8 the responsible person often the pharmacist? At a
9 pharmacy?

10 A. It must be a pharmacist at a pharmacy.

11 Q. But the applicant might be a different
12 person.

13 A. Correct.

14 Q. Such as the owner or CEO of the pharmacy?

15 A. Could be.

16 Q. So on page, I think they are numbered in
17 the upper right.

18 A. Oh, yes.

19 Q. Page 4 has some demographic but let's talk
20 about page 5.

21 A. Yes.

22 Q. These questions pertain to the pharmacy
23 business; is that right?

24 A. Yes.

25 Q. And can you explain some of these

1 questions for me? Pharmacy function, what is this?

2 A. So this is a drop-down list which helps
3 categorize what the majority of the business that the
4 pharmacy conducts are. So they would select one of
5 those.

6 Q. And then the next question is sort of an
7 open text box for business practice.

8 A. Correct.

9 Q. And what sort of information is the Board
10 looking for there?

11 A. What types of medications they send,
12 you'll see that we ask some additional questions
13 later about that. Typically they are expounding on
14 the former question and describing that further.

15 Q. And same thing with patient population?

16 A. Correct.

17 Q. What kind of answers do we typically see
18 with patient population? "We serve the elderly" for
19 example?

20 A. Correct. Another example would be we
21 service hospice patients in an end patient hospice
22 setting would be an example.

23 Q. At the bottom of this page it asks a
24 couple other questions about the pharmacy business;
25 DEA registration, protocols and times, written

1 description. Are these specific to out-of-state
2 pharmacies?

3 A. Yes, they are.

4 Q. And can you maybe help me understand what
5 some of these questions mean? I think DEA
6 registration is pretty self-explanatory. But what
7 does it mean a written description of normal delivery
8 protocols?

9 A. So they have to have, the pharmacy must
10 have policies and procedures in place for how long it
11 takes a prescription or a dispensed medication to get
12 to the patient.

13 Q. And sort of similar protocol in place for
14 packaging; is that right?

15 A. Correct.

16 Q. And then there's a big question at the top
17 of the next page. Can you maybe explain that to me
18 about offer to counsel?

19 A. Yes. Ohio rule requires that pharmacies
20 must offer to counsel patients and so even
21 nonresident pharmacies have to follow that
22 requirement. So the pharmacy must detail how they're
23 going to comply with that requirement.

24 Q. Could you tell me in the sort of the
25 Board's experience most common ways out-of-state

1 pharmacies comply with this are? By phone?

2 A. I would say typically it is by phone since
3 they would be out of state. Some offer a card in the
4 package that would be delivered with the dispensed
5 medication.

6 Q. A card saying what?

7 A. With information on how to contact the
8 pharmacy if the patient has any questions.

9 Q. I see. And then one last question in that
10 section, date of your last inspection. This also is
11 a question sort of specifically for an out-of-state
12 terminal distributor.

13 A. Correct.

14 Q. And that's because the state regulatory
15 agency in their state sort of is responsible for
16 inspecting them?

17 A. Correct.

18 Q. The Ohio State Board of Pharmacy, do they
19 ever inspect an out-of-state terminal distributor?

20 A. Not to my knowledge we never have.

21 Q. I think it's fair to summarize the next
22 couple questions is about the applicant's sort of
23 background. Can you sort of talk about these in
24 general for me?

25 A. Correct. So the next section through most

1 of the end of the application are legal and
2 disciplinary questions. The first section would be
3 for the applicant which does not just include the
4 individual completing the application.

5 Q. It also includes other people.

6 A. Correct.

7 Q. Such as?

8 A. The business owners, any employee with
9 access to drug stock at the applied for location.

10 Q. I'm sorry, can you say that again? Any
11 employee with access to drug stock counts as an
12 applicant?

13 A. Correct.

14 Q. So does this include like pharmacy
15 technicians?

16 A. It could.

17 Q. Depending on.

18 A. Right.

19 Q. And then on the next page is sort of
20 similar questions but for the responsible person.

21 A. Correct.

22 Q. Are these questions, if an entity or an
23 applicant or responsible persons answers "yes" to any
24 of these, does that mean their application is
25 rejected?

1 A. No.

2 Q. And what happens if that happens?

3 A. Well, there are several things that
4 happen. One of the things would be if on the
5 application an affirmative answer to any of these
6 legal or disciplinary questions is answered, they
7 would be required to submit documentation supporting
8 their affirmative answer.

9 Q. Affirmative answer means yes, I was
10 convicted of a crime of moral turpitude.

11 A. Correct.

12 Q. And has it been the case that the Board
13 has approved a license for an entity without
14 disclosing any specifics, has approved a license for
15 an entity even when a person there had previously
16 been convicted of one of these?

17 A. Convicted of one of these?

18 Q. Like for example, question: Has the
19 responsible person ever been convicted of a felony
20 under state law? That's about halfway down page 7.

21 A. It's potential. I can't recall a specific
22 example right now.

23 Q. But if, for example, on that question the
24 entity answered yes, it wouldn't mean their
25 application was rejected automatically.

1 A. Correct.

2 Q. Would they have a hearing on this?

3 A. Potentially.

4 Q. And what goes into that potentiality?

5 A. Depending on the facts of the case and the
6 materials submitted, our Compliance and Enforcement
7 Department would review to determine if further
8 action or a hearing were necessary.

9 Q. Can you tell me what sort of goes into the
10 Board's view whether a hearing is necessary?

11 A. I don't know all of the specifics but it's
12 like I said, investigating the facts that were
13 provided and the materials provided with the
14 application and a further background investigation.

15 Q. Is there a hearing for every time someone
16 applies for a terminal distributor license?

17 A. No.

18 Q. Do you have a sense of what percentage
19 have a hearing?

20 A. I don't. You said "a sense"?

21 Q. Yeah. I don't need an exact percentage
22 but if you could tell me half of all applications.

23 A. A majority, an overwhelming majority of
24 our applications do not have a hearing.

25 Q. I understand. I just want to ask a couple

1 other questions about the end of it starting on
2 page 9. Looks like at the bottom half of that page
3 there are some requirements for verification,
4 inspection. This is also something that applies to
5 the out-of-state terminal distributor applicant? Or
6 does the instate have a similar requirement of
7 providing the most recent inspection report?

8 A. This is only for out-of-state applicants.

9 Q. When the Board receives an application
10 from the out-of-state applicant for a terminal
11 distributor, does the Board ever doublecheck that
12 these things are right? Do they call the State Board
13 of Pharmacy in that other state and say is this
14 correct, is this the most recent one? Or does it
15 sort of rely on the applicant to provide?

16 A. It relies on the materials that the
17 applicant supplies. I will say we can identify a
18 true record from another Board pretty easily, and
19 there are some, there is some information that we do
20 verify with that state board wherever that state is.
21 Or the licensing authority.

22 Q. Sure.

23 A. We verify some of that information.

24 Q. I'm definitely using the shorthand
25 "pharmacy" even though I understand it's broader than

1 just pharmacy.

2 A. Uh-huh.

3 Q. So to summarize what you just said I
4 think, the Board verifies some of that information
5 but in large part feels it can identify things from
6 the documents.

7 A. Correct.

8 Q. Is that fair?

9 A. Yes.

10 Q. Now, I don't have a copy with me for the
11 application for the wholesale distributor. Would you
12 say it's similar to the application we just went
13 through?

14 A. Very similar.

15 Q. I wanted to ask a couple questions for you
16 about sort of the processing of this application once
17 it's submitted. So we've gone through filling it
18 out, the terminal distributor applicant has sent it
19 in. First, do you have an idea how long it takes to
20 fill out an application like this?

21 A. That really depends on the applicant. If
22 you have all of the required materials gathered, it
23 doesn't take long at all, maybe 10-15 minutes.

24 Q. And how long does the Board spend
25 processing this?

1 A. All applications are reviewed within 30
2 days typically. It varies depending on the
3 application how long it will take to review.

4 Q. Could you, does the Board have a sense of
5 the average amount of time it takes to review an
6 application like this?

7 A. The most complex reviews are under 30
8 minutes. But again, we use an online system and
9 sometimes documents are slow to open, so that can
10 vary.

11 Q. In sort of start to finish from submission
12 of the application until granting of the license in
13 the average case how long would that normally take?

14 A. Can you repeat your question?

15 Q. If I submit a license today and I want to
16 know how soon I can hope to get my license as a
17 terminal distributor in Ohio, on average how long
18 would that take?

19 A. You would be informed at least within 30
20 days. Typically we in the Licensing Department are
21 getting applications reviewed and notice of either
22 issuance of the license or incomplete or missing
23 documentation that wasn't supplied appropriately with
24 the application within about two weeks.

25 Q. What happens if there's, if it's

1 incomplete, what does the Board do?

2 A. We email the applicant, sometimes it's
3 followed up by a phone call with the specific
4 information that was incomplete or missing, and we
5 give them a 30-day timeline from the date that email
6 was sent to return the missing information.

7 Q. And if they do, what happens then?

8 A. We continue to process the application.

9 Q. So it sounds sort of like maybe you
10 provide direction to the applicant you're missing
11 these things.

12 A. Yes.

13 Q. And before an application might be
14 rejected, is there a, I think you said there's
15 typically a hearing?

16 A. Can you explain what you mean by
17 "rejected"?

18 Q. Yeah, if the Board said we've reviewed
19 this and we just didn't think this person, we're not
20 certain this person should get a terminal distributor
21 license, or is that question not even the question
22 the Board asks? Maybe I should take a step back.

23 A. Yes, so if from the rejected that you are
24 discussing should the applicant get a license, there
25 would be a hearing on that form of your question.

1 Q. Are there other forms, have I asked the
2 question wrong?

3 A. I think it's important to clarify that
4 sometimes the application might be rejected because
5 the applicant does not meet the qualifications. For
6 example, if the pharmacy is not licensed in their
7 home state and they're out of state and applying for
8 a nonresident pharmacy license, they don't meet the
9 minimum qualifications in rule.

10 Q. I see. And then there might be other
11 reasons though to reject it.

12 A. Correct. Such as past criminal
13 convictions or disciplinary action, that would get a
14 hearing before the full Board.

15 Q. I see. How does the Board sort of weigh
16 that stuff? Is there a lot of discretion involved?

17 A. I can't really say because that's between
18 our Board.

19 MR. APPEL: I was going to object and say
20 ambiguous, if you're asking about the Board are you
21 asking about Board staff or Board members at a Board
22 hearing?

23 Q. I'm asking about just whatever the Board
24 does as far as you're prepared to answer the
25 question. I wasn't distinguishing parts of the

1 Board.

2 When the Board of Pharmacy or its
3 employees get one of these applications and are
4 reviewing it, what sort of factors guide the employee
5 review of the application?

6 A. So the employee is reviewing the same
7 thing for every application, it does not vary between
8 applications. They're looking for the minimum
9 requirements, looking at the legal and disciplinary
10 questions that were answered, were they answered in
11 the affirmative.

12 They're looking for verification of the
13 home state license, again that would be minimum
14 qualifications. And we also look at the, to see if
15 we have any past or current investigations on the
16 responsible person, the applicants, or the business
17 entity themselves.

18 Q. Do you know what percentage of such
19 applications like this are granted? Is it most?

20 A. Yeah, so as of like May of 2018, up until
21 a few weeks ago we granted over 75 percent of
22 applications that were submitted.

23 Q. Would it -- I have a couple other
24 questions about that. Is there any sort of limit in
25 Ohio in the number of these licenses that can be

1 issued? Like we only issue a thousand a year or
2 something like that?

3 A. Not at all.

4 Q. And similarly no limit for an out-of-state
5 entity, we only allow a thousand out-of-state
6 terminal distributors a year?

7 A. That requirement is not in place, or that
8 restriction, excuse me.

9 Q. So I think we've, I want to make sure I
10 have sort of a good sense of all the reasons the
11 Board might not grant an application, and you
12 mentioned -- let me know if I've got all the right
13 things.

14 We have sort of the minimum requirements,
15 being licensed in the home state, ever been
16 disciplined before, answering yes to any of these
17 criminal background check questions. Are there any
18 others that I've missed?

19 A. Well, I did say we look at our case files
20 and our case investigations previous and current to
21 see if the business entity, responsible person, or
22 applicant have ever been a suspect in one of our
23 investigations.

24 Q. I'm sorry, I meant to include that one.
25 So is that all of them then?

1 A. To my knowledge.

2 Q. And so if we can imagine an applicant who
3 doesn't fall in any of those traps, is it fair to,
4 for that person to imagine that they would get a
5 license?

6 A. Absolutely.

7 Q. I wanted to ask you a couple questions
8 about, I think along the same lines about some of the
9 statements the Board made in its, your lawyer made
10 for you in the papers.

11 (EXHIBITS 6 - 7 MARKED.)

12 Q. So Exhibit 6 is a motion filed by the
13 Board through its counsel. I don't know if you've
14 ever seen this before.

15 A. This is the first that I am reviewing it
16 in full.

17 Q. I think one portion of it sort of relates
18 to what we're talking about here, so I want to direct
19 your attention to page 5. And in about the third
20 paragraph down, paragraph beginning with "if," "If an
21 entity applies and meets all requirements, it is
22 entitled as a matter of law to receive a TDDD or WDDD
23 license."

24 Is that an accurate sentence?

25 A. Yes.

1 Q. And then a similar sentence on the next
2 document, Exhibit 7, which is the next thing your
3 counsel filed for the Board, and right on page 1 the
4 very bottom it says a similar thing, these provisions
5 establish that an entity will be eligible for a TDDD
6 license if it meets the minimum requirements and
7 there are no administrative prohibitions, and if
8 there's a question about these the TDDD will be
9 entitled to an administrative hearing.

10 Is that an accurate sentence?

11 A. Yes.

12 Q. "An entity desiring to be licensed in Ohio
13 as a TDDD need only apply and meet the minimum
14 qualifications, unlike other types of licenses that
15 are limited and competitive." Accurate?

16 A. Yes.

17 Q. And lastly, there is no maximum number
18 that the Board can issue, I think you already
19 answered, but that's accurate?

20 A. Yes.

21 Q. So about this sentence, what does the
22 phrase "administrative prohibitions" mean to you in
23 this?

24 A. So in Ohio Revised Code and Ohio
25 Administrative Code the Board of Pharmacy is granted

1 the ability to deny applications for several
2 different reasons.

3 Q. Are those reasons we've already talked
4 about or are there others?

5 A. There might be others.

6 Q. Can you tell me what some of those would
7 be?

8 A. I can't speak specifically to what's in
9 the statute or the rule, as having not memorized it,
10 but for example, if owners of a pharmacy were
11 convicted of drug trafficking, they're likely not
12 going to get a license.

13 Q. I see. Is it the case that typically
14 these administrative prohibitions are related to
15 crimes like this?

16 A. I wouldn't say typical. They could vary.

17 Q. I'm just trying to get a sense of what are
18 the reasons a license could be denied. So do you
19 have another example maybe?

20 A. It would really depend. And again what,
21 the ultimate denial falls to the full panel of the
22 Board, so, and those positions and the terms are
23 varied. So depending on the feeling of the Board,
24 the hearing, the facts of the case, it could very
25 much defer from one application to another

1 potentially.

2 Q. So let me unpack that a little bit. You
3 talked about the Board, the feeling of the Board at a
4 hearing but not all applicants end up going to a
5 hearing.

6 A. Correct.

7 Q. So I guess I don't quite understand the
8 process. Do all applicants end up in front of the
9 full Pharmacy Board or whatever licensing I guess the
10 pharmacy being the Pharmacy Board, are some approved
11 without ever having to go to the Board?

12 A. Absolutely.

13 Q. I see.

14 A. As it states in Exhibit 6 and 7, if the
15 entity meets the minimum requirements and there are
16 no administrative prohibitions, they would be issued
17 their license.

18 Q. Without having to go in front of the whole
19 Board.

20 A. That's correct.

21 Q. The reasons they might have to go in front
22 of the full Board would be these administrative
23 things you mentioned.

24 A. Correct.

25 Q. Such as the owner was convicted of drug

1 trafficking.

2 A. That is one example.

3 Q. And the others are listed in the statute?

4 A. Yes. I wouldn't say examples, reasons to
5 propose to deny or cite an entity would be listed in
6 the statute and rule.

7 Q. So I guess maybe you just answered this
8 question, but my last question on this topic is am I
9 missing anything? I mean I'm not an expert in
10 pharmacy law at all and I don't know if I've covered
11 all the sort of most common reasons that someone
12 might be prevented from getting a terminal
13 distributor license. Do you think we've talked about
14 most of them?

15 A. Yes.

16 Q. There's nothing that I forgot to talk
17 about?

18 A. Nothing that I can think of.

19 Q. Okay. Nothing that I can think of either,
20 which is why I didn't ask any more.

21 A. Okay.

22 Q. The last thing I wanted to point out, the
23 last exhibit we have is the Annual Report for 2018.

24 (EXHIBIT 8 MARKED.)

25 Q. Do you recognize this?

1 A. I do.

2 Q. What is it?

3 A. It's the Board of Pharmacy's Annual Report
4 from fiscal year 2018.

5 Q. So I just wanted to turn your attention to
6 page 4.

7 A. Yes.

8 Q. Are these the most accurate numbers as of,
9 are these numbers accurate for 2018?

10 A. Yes.

11 Q. And is there, will there be another report
12 coming for '19?

13 A. To my knowledge.

14 Q. Do you know when that would be out?

15 A. I'm unsure. When did we release this
16 report last year? It would be probably just after
17 the beginning of the new fiscal year.

18 Q. And the new fiscal year starts in July?

19 A. July 1.

20 Q. So just a couple housekeeping questions I
21 guess. All the, many of the documents we've looked
22 at I mentioned were turned over to us by the Board
23 through its counsel. Were you aware of that?

24 A. Yes.

25 Q. Did you assist in gathering those

1 documents?

2 A. Some of them, yes.

3 Q. Do you feel like there are any that were
4 missing as far as an application for terminal
5 distributor license?

6 A. Missing, no. There might be, like you
7 pulled the E-license Guide for new applicants,
8 there's a lot of information on our website that's
9 publicly available that may assist an applicant in
10 completing the application.

11 Q. But as far as the, I mean I understand
12 that, but as far as the like actual licensing
13 application requirements, we have all the documents?

14 A. Yes.

15 MR. RUSNAK: Can we just have a second to
16 talk.

17 (Off the record.)

18 Q. So I'll try to be quick.

19 A. Okay.

20 Q. I just have a couple of follow-up
21 questions that my colleagues reminded me I didn't ask
22 all the questions.

23 At the end of our conversation before the
24 break we were talking about the statement from the
25 papers about administrative prohibitions. Do you

1 remember that?

2 A. I do.

3 Q. And I just want to make sure that I
4 understand the whole universe of administrative
5 prohibitions. You said, you gave me an example of
6 one problem like being convicted of drug trafficking,
7 right?

8 A. I did.

9 Q. And then you said you don't have the other
10 ones memorized but they're in the statute.

11 A. And Ohio Administrative Code.

12 Q. I understand.

13 A. The statute and rule.

14 Q. Could you just tell me what those are?
15 Could you consult and look at the papers and tell me
16 what the Administrative Code is section that you're
17 talking about?

18 A. I could consult my legal counsel for the
19 appropriate section that we could provide to you.

20 Q. Yeah.

21 MR. APPEL: Do you remember them off the
22 top of your head?

23 MS. DEHNER: For terminal it would be
24 Revised Code 4729.54. And .55. For the
25 Administrative Code you would look at 4729-9-19. And

1 I'm trying to think if there are other specific.

2 MR. APPEL: And obviously this is a
3 professional courtesy to you attorney to attorney,
4 I'm not expecting her to memorize every provision.

5 MR. RUSNAK: I think it was in your
6 papers. 4729:5-2-02(B), and 4729:5-8 for a
7 nonresident were also mentioned in your papers.

8 MS. DEHNER: Say those again.

9 MR. RUSNAK: They have a sort of colon in
10 them.

11 MS. DEHNER: So you're reading our rules.
12 Those are for the minimum quals then.

13 MR. RUSNAK: 4729:5-2-02(B).

14 MS. DEHNER: Yes.

15 MR. RUSNAK: And then 5-8 was the
16 nonresident one.

17 MS. DEHNER: Yes. Those were moved
18 recently from 4729-5 and it went to :5.

19 MR. RUSNAK: There's a reason I don't do
20 admin law.

21 MS. DEHNER: But the disciplinary code on
22 which a Board would base a proposal to deny would be
23 found in -9-19. The minimum quals are the other code
24 sections that you referenced.

25 Q. (By Mr. Rusnak) So do you feel that

1 covers all the things that are meant in the term
2 "administrative prohibitions"?

3 A. Yes.

4 Q. Got it. Perfect.

5 Couple other things. I'm sorry, I'm all
6 over the place. We talked how an application might
7 normally be sort of reviewed and granted in 30 days
8 sometimes.

9 A. Yes.

10 Q. Is there a provision to ask for it to be
11 expedited?

12 A. No.

13 Q. So 30 days is the fastest?

14 A. No, I believe I stated that our typical
15 turnaround is 30 days but often we are reviewing
16 applications and getting them, again that notice of
17 issuance or incomplete missing documentation within
18 about two weeks.

19 Q. Oh, okay. I'm sorry.

20 Maybe I could ask you a little bit about
21 that reviewing process. I don't mean to belabor the
22 point but I'm kind of slow on the uptake on this.
23 The initial review is by an employee; is that right?

24 A. Correct.

25 Q. Like an analyst?

1 A. A licensing coordinator is their title.

2 Q. Licensing coordinator. And if everything
3 is shipshape at that point, since there's no standout
4 administrative prohibitions, where does the
5 application go next? It just gets issued?

6 A. It gets issued to the applicant.

7 Q. So it doesn't have to go in front of a
8 whole Board.

9 A. No.

10 Q. When would it go to the whole Board?

11 A. Only if it were being proposed to be
12 denied due to administrative prohibition.

13 Q. Would it go to the full Board or sort of a
14 subpanel of the Board?

15 A. So the process is that it doesn't go
16 straight to the Board, it would be referred to our
17 Compliance and Enforcement Department for further
18 investigation. They would conduct interviews, pull
19 some certified court documents if that were
20 applicable.

21 After that our Compliance and Enforcement
22 Department would review the facts of the case with
23 our Legal Department and based on past precedent and
24 the administrative prohibitions that are in statute
25 and rule, they would make the determination if a

1 hearing needed to be had. Meaning if they were going
2 to move forward with a proposal to deny the
3 application.

4 That then would be presented to a
5 committee called Citation Review which is typically
6 the Board president and sometimes the Board vice
7 president, where the facts of the case would be
8 presented to him or her and a determination of
9 proceeding or issuing a license would be made.

10 It would be after that determination if
11 proceeding would be the decision a notice of
12 opportunity for hearing would be issued to the
13 applicant to which there is a time period where the
14 applicant would need to formally request a hearing
15 before the full Board, which would then subsequently
16 be scheduled before the full Board for their hearing.

17 Q. Maybe I already asked this, but do you
18 have a sense of what percentage of applications end
19 up running through this entire process?

20 A. So I'd actually like to refer to one of
21 your exhibits, which is our Annual Report, which is
22 Exhibit 8.

23 Q. Yeah.

24 A. As I feel it is the best to, let me find
25 it. So on page 6 you'll see Administrative Actions

1 in Fiscal Year 2018. And you'll see that this
2 encompasses all of our license types, not just
3 terminal distributors and not just nonresident
4 pharmacies or even instate pharmacies. That the
5 Board issued 48 citations, and proposals to deny,
6 this is new reciprocal pharmacists or renewal
7 applications was 25.

8 Q. So would that 25 with the TDDD be included
9 in there?

10 A. They would be included in there. And too
11 for sake of clarification, that is a full proposal to
12 deny. The Board may enter into a settlement
13 agreement, as you see, or which could include the
14 applicant withdrawing their application.

15 Q. For most people who apply though is this a
16 pretty easy process?

17 A. I would say so.

18 Q. I just had a -- I wanted to come back to I
19 asked you earlier about the distinction between
20 terminal distributor which you've been talking about
21 most of the time and the wholesale distributor. I
22 think I asked you how those licenses' application
23 processes are different. And we talked about?

24 A. The licenses.

25 Q. Right. That's what I meant to say, we

1 talked about distributing to an end user versus to
2 another wholesaler to a terminal distributor; is that
3 right?

4 A. That is correct.

5 Q. Are there other differences that I'm not
6 talking about that I haven't mentioned?

7 A. There are many. One being in how they
8 would, their recordkeeping that they have to keep; a
9 wholesale distributor doesn't have prescription
10 records and dispensing records but yet a pharmacy
11 would. So that would be one example.

12 Q. Can you think of another one?

13 A. Rules and regulations are different, so
14 for wholesale distributors the officers and owners
15 have to undergo a background check, whereas
16 pharmacies do not.

17 Q. For their application are there, can you
18 tell me what the key differences are in how they
19 apply for those licenses?

20 A. The process of applying is the same
21 through E-license. Again, one of the main
22 differences in processing of the application is the
23 wholesale distributors have, their officers and
24 owners have to undergo a background check, a criminal
25 records check both BCI and FBI, that's Bureau of

1 Criminal Identification and Investigation, and
2 Federal Bureau of Investigation.

3 Wholesale distributors aren't asked a
4 compounding question because only a particular type
5 of wholesale distributor is eligible to compound and
6 that is known as an outsourcing facility. Which is
7 defined by the FDA.

8 Similarity would be that both the
9 pharmacy, the terminal distributor that's out of
10 state and the wholesale distributor that's out of
11 state would have to have licensure in their states.

12 One caveat for the wholesale distributor
13 is if their home state doesn't license them, they
14 have a means to obtain that through the National
15 Association of Boards of Pharmacy through their
16 verified, called VAWD, V-A-W-D, and I'm trying to
17 remember the acronym. I believe it's Verified
18 Accredited Wholesale Distributor program.

19 Q. Even if they're not licensed in their
20 state.

21 A. Correct. Third-party logistics providers
22 and virtual wholesalers are required by
23 Administrative Code to obtain this VAWD accreditation
24 if their home state doesn't license them. That does
25 not apply to terminal distributors.

1 Q. For terminal distributors we talked about
2 out of state but I guess one thing I forgot to ask
3 about is are terminal distributor licenses to
4 distribute in Ohio issued to people outside the
5 country?

6 A. I don't recall any that are currently
7 active.

8 Q. But there's no prohibition on it.

9 A. Not explicitly in statute or rule.

10 Q. But it's not very common.

11 A. Correct.

12 Q. For the out of state, putting aside out of
13 country but for out-of-state terminal distributors we
14 talked about the requirement that they provide
15 counseling.

16 A. Patient counseling.

17 Q. And you said they have a phone number that
18 they could call, right? Is that right?

19 A. That, I believe that is one of the
20 acceptable forms of offering patient counseling.

21 Q. Are there other ways that we haven't
22 talked about? Could they have a person instate
23 sometimes?

24 A. They could. I would have to review that
25 requirement that's stated in the rule to see what

1 would be acceptable.

2 Q. Okay. What is it like if the
3 distributor's not really selling, not that frequently
4 selling to patients so there's no one that would be
5 needing to call, is it any different?

6 A. The wholesale distributor would not be
7 selling to patients.

8 Q. What if they were selling to the State.

9 A. Well, the wholesale distributor doesn't
10 have the patient counseling requirements.

11 Q. Right. Does a terminal distributor ever
12 sell to the State of Ohio though?

13 A. I couldn't say but a terminal distributor
14 making a wholesale sale would be to the State, not
15 the end patient, would not be required to offer
16 patient counseling because of the wholesale sale.

17 Q. I guess what I'm kind of wondering about
18 is would the requirement to offer counseling be
19 different if the drugs were being sold to be used in
20 an execution?

21 MR. APPEL: I'm going to object that's
22 beyond the scope of Paragraph 1 of the attachment.
23 She can answer if she knows.

24 A. Can you repeat your question, please?

25 Q. Yeah. The process, one of the

1 requirements of having a TDDD license if you're out
2 of state is that you provide counseling to, you have
3 a system set up to provide counseling; is that right?

4 A. I believe so, yes.

5 Q. Would that requirement for getting a
6 license be different if the out-of-state entity
7 intended only to sell drugs to the State of Ohio for
8 use in an execution?

9 MR. APPEL: Same objection. You can
10 answer.

11 A. At that point the terminal distributor is
12 making a wholesale sale to the State of Ohio. So
13 again, the offer to counsel the patient would not be
14 required, would not be in play.

15 Q. And terminal distributors are allowed to
16 make a wholesale sale?

17 A. Some are allowed within rule. Ohio allows
18 other states and federal law may oppose our rule or
19 may come into, may contradict our rule. So the
20 business entity themselves has to, with consult of
21 legal counsel make that determination.

22 Q. Last question I had, we talked about the
23 documents that we got from you guys, from the Board.
24 You said a lot of them are available on your website,
25 like the E-license Guide.

1 A. Yes.

2 Q. Are these like, the applications like this
3 sample Exhibit 3 and 4, are those available on your
4 website?

5 A. The sample application has not yet been
6 posted to our website. It's our plan to post samples
7 of all of our applications along with inspection
8 guides. But that was produced for you all as part of
9 the subpoena.

10 Q. So when these are posted if we can get one
11 from your website, those are the real version on your
12 website. We can trust what we get from your website
13 is the real thing?

14 A. Yes.

15 Q. Okay. I did have one thing. I guess it
16 was just the thing you were just saying there at the
17 end when I was asking about wholesale and WDDD and
18 terminal distributors and I asked can a terminal
19 distributor make a wholesale sale.

20 A. Uh-huh.

21 Q. And you said it depends. Can you talk a
22 little more about that?

23 MR. APPEL: Same objection as before.
24 This is outside the scope of her role as a 30(B)(6)
25 witness because that's beyond what was identified,

1 but she can answer if she knows.

2 A. So in Ohio rule a pharmacy is allowed I
3 believe the percentage is 5 percent of their total
4 sales to make wholesale transactions. There are
5 allowances for intercompany transfers and transfers
6 between licenses of common ownership. So to answer
7 your question, yes, a terminal distributor can make a
8 wholesale sale.

9 Q. Let me ask another question, and this
10 might also be beyond what you've prepared to answer
11 today but I'm really curious. I didn't think that a
12 sale to the State of Ohio for use in an execution
13 drug would be a wholesale sale. Could you tell me
14 how I would know if a sale is a wholesale sale or a
15 terminal sale?

16 MR. APPEL: Same objection, this is beyond
17 the scope as her role as a 30(B)(6) witness. You can
18 answer if you know.

19 A. One way that I know would be a wholesale
20 sale does not come by order of prescription and is
21 not dispensed patient specific. A wholesale sale
22 comes as it came from the manufacturer. So it
23 wouldn't have a patient's name or the dispensing
24 pharmacy, it wouldn't have a prescription label on
25 it.

1 Q. Are there others?

2 A. I'm sure there are others. That's the
3 ones that I can think of right now.

4 Q. Okay.

5 A. The main distinction.

6 Q. Sure. Okay, great. I think those are all
7 the questions I had. I really appreciate your time.

8 MR. SCHNEIDER: I have nothing on behalf
9 of the State.

10 MR. RUSNAK: Do you think you could
11 provide us the fiscal year report for '19 when comes
12 out?

13 MR. APPEL: Sure.

14 Q. I think those were all the other documents
15 responsive to the subpoena. Sounds like you looked
16 through most of the documents. You said you were
17 involved in collecting these documents that I've been
18 showing that were produced to us.

19 A. Some of them.

20 Q. So I don't know, I guess I'm asking are
21 you aware of any documents that should have been
22 produced to us?

23 A. That should have been? No. Could be,
24 yes. Again, anything on our website we could provide
25 to you or you could gather yourself, as I'm sure, I

1 don't know if the E-license Guide, I think you said
2 it was not provided to you but you found it.

3 Q. You did say if it's on your website that's
4 the correct version.

5 A. That is correct.

6 MR. RUSNAK: Thanks very much.

7 (Whereupon, at 11:05 a.m., the deposition
8 was concluded and signature was not waived.)

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AFFIDAVIT

State of Ohio)
) SS:
County of _____)

I, KARRIE SOUTHARD, do hereby certify that I have read the foregoing transcript of my deposition given on Tuesday, June 11, 2019; that together with the correction page attached hereto noting changes in form or substance, if any, it is true and correct.

KARRIE SOUTHARD

I do hereby certify that the foregoing transcript of the deposition of KARRIE SOUTHARD was submitted to the witness for reading and signing; that after she had stated to the undersigned Notary Public that she had read and examined her deposition, she signed the same in my presence on the _____ day of _____, 2019.

Notary Public

My commission expires _____, _____.

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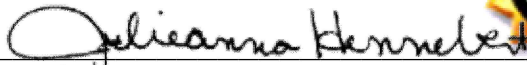
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CERTIFICATE

State of Ohio)
) SS:
County of Franklin)

I, Julieanna Hennebert, RPR and RMR, the undersigned, a duly qualified and commissioned notary public within and for the State of Ohio, do certify that, before giving her deposition, KARRIE SOUTHARD was by me first duly sworn to testify to the truth, the whole truth, and nothing but the truth; that the foregoing is the deposition given at said time and place by KARRIE SOUTHARD; that I am neither a relative of nor employee of any of the parties or their counsel and have no interest whatever in the result of the action.

IN WITNESS WHEREOF, I hereunto set my hand and official seal of office on this 14th day of June, 2019.


Julieanna Hennebert, RPR, RMR,
and Notary Public in and for the
State of Ohio.



My commission expires February 19, 2023.
(2921-JLH)

--|--

AFFIDAVIT

State of Ohio)
) SS:
 County of Franklin)

I, KARRIE SOUTHARD, do hereby certify that I have read the foregoing transcript of my deposition given on Tuesday, June 11, 2019; that together with the correction page attached hereto noting changes in form or substance, if any, it is true and correct.

Karrie Southard
 KARRIE SOUTHARD

I do hereby certify that the foregoing transcript of the deposition of KARRIE SOUTHARD was submitted to the witness for reading and signing; that after she had stated to the undersigned Notary Public that she had read and examined her deposition, she signed the same in my presence on the 25th day of June, 2019.

Nicole DeHine
 Notary Public

My commission expires N/A NICOLE DEHINE,
 Attorney At Law

-- | Notary Public, State of Ohio
 My commission has no expiration date
 Sec. 147.03 R.C.

ERRATA SHEET

Please list any changes to your deposition below. Be sure to list the page, line, description of change and the reason for your change. Please sign and date when complete. While the changes are not physically made to the transcript, the errata sheet is forwarded to the ordering attorney and will be added as an addendum to your transcript.

<u>PAGE</u>	<u>LINE</u>	<u>DESCRIPTION OF CHANGE</u>	<u>REASON FOR CHANGE</u>
<u>10</u>	<u>23-24</u>	<u>A: Correct, all except Schedule 1</u>	<u>Line 24 attributable to</u> Karrie Southard, Answer in Line 25 "sure" was by Questioning attorney
<u>20</u>	<u>21</u>	<u>"...in in-patient hospice..."</u>	<u>change from "end patient"</u> to "in-patient"
<u>35</u>	<u>25</u>	<u>change defer to "differ"</u>	<u>typo</u>
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Karrie Southard
Signature

6/25/19
Date